

WEST et al  
Appl. No. 10/517,653  
November 25, 2008

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**REMARKS/ARGUMENTS**

Reconsideration of this application is requested. Claims 1 and 3-17 are in the case.

**I. THE INTERVIEW**

At the outset, the undersigned wishes to thank the Examiner (Mr. Kolker) for kindly agreeing to conduct an interview in this case. The interview was held on October 30, 2008, and the courtesies extended by the Examiner were most appreciated.

The substance of the interview will be clear from the Interview Summary as well as the further comments presented below. In particular, a possible amendment of claim 1 to refer to a method of stimulating "axonal outgrowth" as opposed to a method of stimulating "neuronal regenerative growth or repair" was considered as well as the possibility of limiting claim to administration to living neurons. The Examiner indicated that such an amendment would likely be sufficient to overcome the rejection of record under 35 U.S.C. §112, first paragraph. A possible amendment of claim 1 to methods comprising "direct contact" of the MT-IIA with the neurons or neuronal area was also discussed, and the Examiner indicated that such an amendment would likely be sufficient to overcome the prior art rejections of record. The Examiner cautioned that claims limited to direct contacting had not previously been searched, as claims which recited this language (e.g. claim 13) also allowed for other alternative routes of administration. The following further comments are offered.

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## **II. THE PRIOR ART AND FORMAL REJECTIONS**

### **A. The Rejections**

(a) Claims 1, 2, 4 and 13 stand rejected under 35 U.S.C. §102(b) as allegedly anticipated by or, in the alternative, under 35 U.S.C. §103(a) as allegedly unpatentable over Penkowa (2002; Journal of Comparative Neurology 444(2):174-189) as evidenced by Sigma M9542 and Garrett (2000; The Prostate 43:125-135). Claims 1, 2, 4, 13 and 17 stand rejected under 35 U.S.C. §102(b) as allegedly anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over Giralt (2002; Experimental Neurology 173:114-128, available online 25 February, 2002). Claims 1, 2, 4 and 6-13 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Penkowa (2002; Journal of Comparative Neurology 444(2):174-189). Claims 1-13 and 18-27 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Penkowa (2002; Journal of Comparative Neurology 444(2):174-189). Claims 1-13 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Penkowa (2002; Journal of Comparative Neurology 444(2):174-189) in view of FR 2813529 cited in the IDS dated December 13, 2004. Claims 1, 2, 4, 6-13 and 15 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Penkowa (2002; Journal of Comparative Neurology 444(2):174-189) in view of Asanuma (2002; Neuroscience Letters 327:61-65; available online 21 April 2002). Claims 1, 2, 4, 6-14 and 16 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Penkowa (2002; Journal of Comparative Neurology 444(2):174-189) in view of Walsh (U.S. Patent Application Publication 2002/0155170, published 24 October 2002, filed 30 November 2001, claiming benefit of a provisional application filed 30 November 2000).

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(b) Claims 1-13 stand rejected under 35 U.S.C. §112, first paragraph, because the specification, while being enabling for a method of increasing axonal growth following administration of MT-IIA, allegedly does not reasonably provide enablement for "a method of stimulating regenerative growth" as recited in claim 1. The prior art and formal rejections are respectfully traversed.

**B. The Argument**

Based on the outcome of the interview, and in order to expedite prosecution, the invention as now claimed provides a method of stimulating axonal outgrowth comprising directly contacting a target living neuron or live neuronal area with a solution of the metallothionein isoform MT-IIA. Basis appears in the originally filed specification at page 5, lines 1-5 (axonal outgrowth), page 3, line 8 and claim 2 ("direct contact"). Claim 2 has been canceled without prejudice. All matter canceled has been deleted without prejudice to the possibility of presenting that subject matter in a separate continuing application. No new matter is entered.

As noted above, an outcome of the interview was that amendment to refer to a method of stimulating "axonal outgrowth" along with administration to living neurons would likely be sufficient to overcome the outstanding rejection under 35 U.S.C. §112, first paragraph. A further outcome of the interview was that amendment to specify "direct contact" of the MT-IIA with the neurons or neuronal area would likely be sufficient to overcome the prior art rejections of record.

In light of the indications in the interview summary, it is believed that the outstanding formal and prior art rejections have been obviated by the claim

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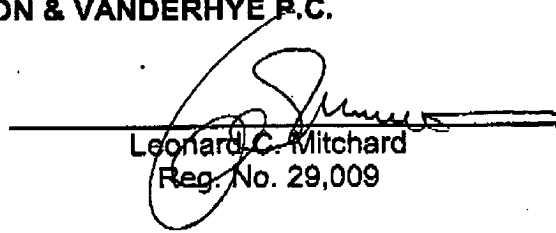
amendments presented herewith. Withdrawal of the rejections is accordingly respectfully requested.

Favorable action is awaited.

Respectfully submitted,

**NIXON & VANDERHYE P.C.**

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